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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,064	10/31/2001	Carolyn Elizabeth Lister	01288.0016	4565

7590

12/29/2004

Finnegan Henderson Farabow Garret & Dunner
1300 I Street NW
Washington, DC 20005

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,064

Applicant(s)

LISTER ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 9 September 2004.
2. Applicant has cancelled claims 13 and 15, and amended claims 1, 2, 7 and 10. Claims 1-12 and 14 are pending, and are examined in the instant action.
3. This action is made FINAL.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, second paragraph

6. Claims 1-12 and 14 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons of record. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Claim 1 is unclear in that the method recites, sequentially, starts with (line 3) a method of transforming embryo cells, then goes to embryo tissue (line 6), to the embryos (line 7), transgenic plant cells (line 11), to the tissues (line 12), and to transgenic plant material. It is unclear what cells' or tissue or explant is used in each step, where it came from and what it produces. This is a reason for the rejections based on lack of antecedent basis. Plant transformation methods, by necessity, since

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they are carried out in vitro, follow an orderly sequence of steps. This needs to be clarified by Applicant.

Claim 1 is drawn to a method of transforming a ... plant comprising (a) transforming embryo cells....

by step (i) recites "embryo tissue", step (ii) recites "embryos"

In claims 1, and 7, step (iii) "cocultivation for a period of 1-12 days" is confusing because the time of beginning of the cocultivation is not given. Does the time begin at step (i), or (ii) or at (iii), or at some other time?

What is a "preparation of Agrobacterium" ? Is it a suspension?

Line 7, "the embryos" lacks antecedent basis.

Line 8, what is co-cultivated with what?

Line 9, "the transformed plant material" lacks antecedent basis

Line 11, "the transgenic plant cells" lacks antecedent basis Line

(b)(iii)

In claim 2, the phrase "and following this transformation, Allium tissue is regenerated by preferential selection" does not make sense here. It is suggested that this language be deleted.

Claim 7 has problems similar to claim 1: In line 4, "embryo tissue" lacks antecedent basis. In line 8, "the embryos" lacks antecedent basis. In line 16,

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“transgenic cultures” of what” cells? embryo tissue? embryos? It is unclear what cells or tissue or explant is used in each step, when it came from and what it produces. This is a reason for the rejections based on lack of antecedent basis. Plant transformation methods, by necessity since they are carried out in vitro, follow an orderly sequence of steps. What is intended by “putative transgenic cultures” and how are they selected needs to be clarified by Applicant.

In claim 10, line 1-2, “DNA conferring” needs to be inserted in front of “herbicide”, and the language “DNA of interest” needs to be deleted, for clarity.

In claim 11, line 2, “of interest is” needs to be replaced by “encodes”, for clarity. The phrase “DNA of interest” needs to be deleted—it is redundant and confusing.

In claim 12, “DNA encoding” needs to be inserted in front of “antibiotic”, “DNA of interest is the” needs to be replaced by “encodes”, and the final “DNA of interest” needs to be deleted, for clarity.

Claims 1 and 7, and all claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. A time duration for coculture (see step (b)(i)), the step(s) of wounding, the light/dark growth conditions where relevant, are essential steps and need to be set forth in the claims.

Claim Rejections - 35 USC § 112, first paragraph

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7. Claims 1-12 and 14 remain rejected under 35 U.S.C. 112, first paragraph. This rejection is maintained for the reasons of record as set forth in the Office Action mailed 20 April 2004. Applicant's arguments filed 09 September 2004 have been fully considered, but are not deemed persuasive.

To the extent that the rejection was made to the scope of all "Allium species plants" as opposed to "Allium cepa", the rejection is maintained in view of Applicant's amendments to the claims.

Reiterating, from the Office Action of 20 April 2004:

Applicant teaches (specification pages 5, lines 11 to page 6, line 14), the method outlined below:

- use immature embryos of Allium cepa L. ,
- use of Agrobacterium LBA4404 bearing the binary vector pBIN-m-gfp-ER or other binary vector, Agrobacterium cultures grown to log phase, storage in glycerol at -80 , overnight Agrobacterium cultures treated with 100 uM acetosyringone, cocultivation mix containing 200 uM acetosyringone.
- isolated immature embryos cut into 1mm sections and transferred to 0.8 ml Agrobacterium and vortexed for 30 seconds, embryo Agrobacterium mix vacuum infiltrated (20 in. Hg) for 30 min before blotting and transferring to solid P5 medium.
- cocultivation for 6 days, after which embryo pieces transferred to selection (geneticin, 10 mg/L; or basta 5 mg/l) plus timetin (200).
- embryo pieces cultured in the dark under the same conditions as (Eady, 1998), transferred to fresh medium every 2 weeks. After 3-4 transfers, material transferred to P5 medium + 25 mg/l geneticin or 5 mg/l Basta, and further grown for weeks.

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- putative transformed plant tissue transferred to regeneration medium (Eady 1988).
- shoot cultures maintained for 12 weeks and developing shoots transferred to medium to induce rooting.

While the specification can provide clarification of elements which are known to one skilled in the art, *essential steps and conditions not known to one of ordinary skill in the art are unpredictable, and must be recited in the claims*, this includes time duration, temperature and concentrations.

In this case, a time duration for coculture (see step (b)(i)), the step(s) of wounding, the light/dark growth conditions where relevant, are essential steps and need to be set forth in the claims.

Applicant is enabled for the scope of *Allium cepa* L. (onion) but not for the scope of all *Allium* plants, as discussed previously.

Applicant's claims, as of this present amendment, are in much better condition.

Remarks

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

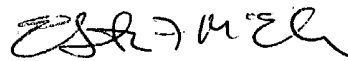
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
December 26, 2004


ELIZABETH MCELWAIN
PRIMARY EXAMINER